Current claim summary

1- 48 (canceled)

49. (previously presented) A controlled release dosage form, comprising:

(a) a core comprising an osmotic agent and a low solubility drug in the form of a solid dispersion of said drug in a dispersion polymer, at least a major portion of said drug being amorphous, wherein said drug in said solid dispersion exhibits amorphous character in at least one of x-ray diffraction analysis or differential scanning calorimetry;

(b) a water-permeable coating around said core having at least one delivery port therein, said coating controlling the influx of water to said core from an aqueous environment of use to cause extrusion of at least a portion of said core through said at least one delivery port to said aqueous environment of use, said coating being non-dissolving and non-eroding during release of said drug;

wherein said dispersion polymer is a cellulosic polymer.

50. (previously presented) The dosage form of claim 49 wherein substantially all of said drug is amorphous.

51. (previously presented) The dosage form of claim 49 wherein said solid dispersion is homogeneous.

52. (previously presented) The dosage form of claim 49 further comprising an osmotically effective solute.

53. (previously presented) The dosage form of claim 49 wherein said osmotic agent and said solid dispersion are in respective discrete portions of said dosage form.

54. (previously presented) The dosage form of claim 53 wherein said osmotic agent is in a first layer and said solid dispersion is in a second layer.

55. (previously presented) The dosage form of claim 49 wherein said osmotic agent comprises a water-swellable hydrophilic polymer that is separate from said dispersion polymer.

56. (previously presented) The dosage form of claim 55 wherein said water-swellable hydrophilic polymer is selected from the group consisting of hydrophilic vinyl and acrylic

polymers, polysaccharide alginates, poly(ethylene oxide), polyethylene glycol, polypropylene glycol, poly(2-hydroxyethyl methacrylate), poly(acrylic) acid, poly(methacrylic) acid, polyvinyl pyrrolidone, crosslinked polyvinyl pyrrolidone, polyvinyl alcohol, polyvinyl pyrrolidone/polyvinyl alcohol copolymers, vinyl acetate, hydrophilic polyurethanes containing large polyethylene oxide blocks, carrageenan, hydroxethyl-cellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose, carboxymethylcellulose, carboxyethylcellulose, sodium alginate, polycarbophil, gelatin, xanthan gum, sodium croscarmellose, and sodium starch glycolate.

57. (previously presented) The dosage form of claim 49 wherein said solid dispersion is formed by spray-drying said low-solubility drug and said dispersion polymer together in a solvent.

58. (previously presented) The dosage form of claim 49 wherein said dispersion polymer is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, and carboxymethylethylcellulose.

59. (previously presented) The dosage form of claim 49 wherein said dispersion polymer is hydroxypropylmethyl cellulose acetate succinate.

60. (previously presented) The dosage form of claim 49 wherein said dosage form provides an AUC in a use environment that is at least 1.25-fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug.

61. (previously presented) The dosage form of claim 49 wherein said dosage form is dosed orally to a mammal, said dosage form provides an AUC in drug concentration in the blood that is at least 1.25-fold that of a control dosage form comprising an identical dosage form except containing an equivalent quantity of undispersed drug.

62. (previously presented) The dosage form of claim 49 wherein said drug is selected from the group consisting of an anti-hypertensive, and antianxiety agent, an anticlotting agent, a blood glucose-lowering agent, a decongestant, an antihistamine, an antitussive, an anti-inflammatory, an anti-atherosclerotic agent, an antipsychotic agent, a cognitive enhancer, a cholesterol-reducing agent, an antiobesity agent, an autoimmune disorders agent, a hypnotic agent, an anti-Parkinsonism agent, an antibiotic, an antiviral agent, an

anti-impotence agent, an anti-neoplastic, a sedative, a barbituate, a nutritional agent, a beta-blocker, an emetic, an anti-emetic, a diuretic, an anticoagulant, a cardiotonic, an androgen, a corticoid, an anabolic agent, an anti-depression agent, an anti-infective agent, a coronary vasodilator, a carbonic anhydrase inhibitor, an antifungal, an antiprotozoal, a gastrointestinal agent, a dopaminergic agent, an anti-Alzheimer's Disease agent, an anti-ulcer agent, a platelet inhibitor, and a glycogen phosphorylase inhibitor.

63. (previously presented) A controlled release dosage form, comprising:

(a) a plurality of multiparticulates, each of said multiparticulates comprising a core surrounded by a water permeable coating that is non-dissolving and non-eroding, said coating having a delivery port formed in situ during use or by rupture during use;

(b) said core comprising a low-solubility drug in the form of a solid dispersion of said drug in a dispersion polymer, at least a major portion of said drug being amorphous, wherein said drug in said solid dispersion exhibits amorphous character in at least one of x-ray diffraction analysis or differential scanning calorimetry; and

(c) said core further comprising an osmotic agent separate from said dispersion polymer.

64. (previously presented) The dosage form of claim 63 wherein said solid dispersion is in the form of particles distributed throughout said core.

65. (previously presented) The dosage form of claim 63 wherein said solid dispersion comprises a coating surrounding a seed core.

66. (previously presented) The dosage form of claim 63 further comprising a meltable excipient.

67. (previously presented) The dosage form of claim 65 wherein said seed core comprises a meltable excipient.

68. (previously presented) The dosage form of claim 67 wherein said seed core comprises said osmotic agent.

69. (previously presented) The dosage form of claim 63 wherein said core is formed by melt-congealing from a spinning disk.

70. (previously presented) The dosage form of claim 63 wherein said osmotic agent comprises a water-swellable polymer that is separate from said dispersion polymer.

71. (previously presented) The dosage form of claim 68 wherein said water-swellable polymer is selected from the group consisting of hydrophilic vinyl and acrylic polymers, polysaccharide alginates, poly(ethylene oxide), polyethylene glycol, polypropylene glycol, poly(2-hydroxyethyl methacrylate), poly(acrylic) acid, poly(methacrylic) acid, polyvinyl pyrrolidone, crosslinked polyvinyl pyrrolidone, polyvinyl alcohol, polyvinyl pyrrolidone/polyvinyl alcohol copolymers, vinyl acetate, hydrophilic polyurethanes containing large polyethylene oxide blocks, carrageenan, hydroxethyl-cellulose, hydroxypropylcellulose, hydroxypropylmethyl-cellulose, carboxymethylcellulose, carboxyethylcellulose, sodium alginate, polycarbophil, gelatin, xanthan gum, sodium croscarmellose, and sodium starch glycolate.

72. (previously presented) The dosage form of claim 63 wherein said dispersion polymer is selected from the group consisting of:

(a) ionizable cellulosic polymers;

(b) nonionizable cellulosic polymers; and

(c) vinyl polymers and copolymers having substituents selected from the group consisting of hydroxyl, alkylacyloxy and cyclicamido.

73. (previously presented) The dosage form of claim 72 wherein said dispersion polymer comprises hydroxypropylmethyl-cellulose, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, carboxymethylethyl cellulose, polyvinyl pyrrolidone, polyvinyl alcohol, and copolymers of polyvinyl pyrrolidone and polyvinyl alcohol.

74. (previously presented) The dosage form of claim 72 wherein said dispersion polymer is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, and carboxymethylethylcellulose.

75. (previously presented) The dosage form of claim 63 wherein said dispersion polymer is hydroxypropylmethyl cellulose acetate succinate.

76. (previously presented) The dosage form of claim 63 wherein said solid dispersion is formed by spray-drying said low-solubility drug and said dispersion polymer together in a solvent.

77. (previously presented) The dosage form of claim 63 wherein said drug is selected from the group consisting of an anti-hypertensive, and antianxiety agent, an anticlotting agent, a blood glucose-lowering agent, a decongestant, an antihistamine, an antitussive, an anti-inflammatory, an anti-atherosclerotic agent, an antipsychotic agent, a cognitive enhancer, a cholesterol-reducing agent, an antiobesity agent, an autoimmune disorders agent, a hypnotic agent, an anti-Parkinsonism agent, an antibiotic, an antiviral agent, an anti-impotence agent, an anti-neoplastic, a sedative, a barbituate, a nutritional agent, a beta-blocker, an emetic, an anti-emetic, a diuretic, an anticoagulant, a cardiotonic, an androgen, a corticoid, an anabolic agent, an anti-depression agent, an anti-infective agent, a coronary vasodilator, a carbonic anhydrase inhibitor, an antifungal, an antiprotozoal, a gastrointestinal agent, a dopaminergic agent, an anti-Alzheimer's Disease agent, an anti-ulcer agent, a platelet inhibitor, and a glycogen phosphorylase inhibitor.

78. (previously presented) The dosage form of claim 63 wherein said core, when exposed to an aqueous use environment, swells and ruptures said coating.